

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2025-0509

#### 0 4 JUN 2025

# TO : ALL CONCERNED HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES STAKEHOLDERS

# SUBJECT : Regulatory Updates for Household/Urban Hazardous Substances (HUHS)

The Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) of the Food and Drug Administration (FDA) hereby informs household/urban hazardous substances (HUHS) stakeholders of the following regulatory updates:

### 1. Extension of the Transitory Period for HUHS Product Registration and Labeling Requirements

With a recognition of the appeals and regulatory challenges from the HUHS industry posited to the Agency regarding FDA Circular No. 2020-025, the FDA has previously extended regulatory flexibilities to assist stakeholders in complying with regulations, including safety, efficacy and quality standards. The FDA further shares that it likewise continuously monitors the implementation of FDA Circular No. 2020-025 and conducts policy reviews which aim to further assist the industry in their challenges with the registration and labeling requirements.

In view of renewed appeals from the HUHS industry, the FDA hereby announces the following further regulatory flexibilities:

a. In securing a Certificate of Product Registration (CPR) and bringing HUHS products into conformity with the labeling requirements under Annex J of the same Circular, the transitory period provided in DOH Administrative Order No. 2019-0019 will further be extended <u>until 31 December 2025</u>.

During the extended transitory period, HUHS establishments are allowed to continue the distribution of their HUHS products without a CPR from the FDA, provided that they have obtained the appropriate License to Operate (LTO). While an extension of the transitory is in place, the FDA strongly encourages all HUHS establishments with pending registration applications to submit all compliance documents within the prescribed timeline to facilitate timely issuance of final decisions.

b. Further, through FDA Advisory No. 2024-1660, previously issued CPRs are eligible for an extended validity period until 30 June 2025 following the interim procedure provided therein. Stakeholders are likewise encouraged to proceed with their respective automatic renewal CPR applications through the procedure outlined under FDA Advisory No. 2025-0504, launched on 2 May 2025.

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### 2. On-boarding of the Updated HUHS Licensing Process on to the FDA eServices Portal System

The FDA is pleased to announce that the onboarding of the licensing process for HUHS establishments on the FDA eServices Portal system is in its final stages of testing. The said licensing process shall be available **by 2 June 2025**. Further, **beginning this date**, all HUHS LTO initial, renewal and variation applications shall be exclusively filed and accepted through the FDA eServices Portal System at <a href="https://eservices.fda.gov.ph/">https://eservices.fda.gov.ph/</a>, following the guidelines provided under Department of Health (DOH) Administrative Order No. 2024-0015.

For ease in transition, all previously-issued HUHS LTOs which expired or will be expiring before 01 July 2025 may be **automatically renewed with validity period <u>until 30 June</u> <u>2025</u> with waived surcharges, provided that, prior 30 May 2025</u> a "Letter of Request and Declaration Statement" following the format of Annex G of FDA Advisory No. 2024-0543, which signifies intention to submit an LTO renewal application in the FDA eServices Portal System once available, is submitted to the Food and Drug Action Center (FDAC) through email at fdac@fda.gov.ph.** 

For information and guidance.

ATTY. P **OLO S. TESTON** ifector General